AUG 1 1 2003

K032001

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter

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Federal State:	Bavaria
Country:	Germany
Establishment Registration Number:	9611385
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Date:	June 17, 2003

Name of Device

Proprietary Name:	Poly Q Garant™ L Poly Q Penta™ M Poly Q Penta™ H
Classification Name	Impression material
Common Name:	Dental impression material

Predicate Device:

Poly Q Garant™ L:	Impregum™ Garant™ L DuoSoft, K 994190
Poly Q Penta™ M:	Impregum™ Penta™ M Monosoft, K 994192
Poly Q Penta™ H:	Impregum™ Penta™ H DuoSoft, K 994193

Description for the Premarket Notification

Poly Q is classified as Impression material (21 C.F.R. § 872.3660) because it is a device intended to reproduce the structure of a patient's teeth.

Poly Q will be available in three different viscosities, called Poly Q Garant™ L (light body), Poly Q Penta™ M (medium body) and Poly Q Penta™ H (heavy body).

Poly Q Penta M and Poly Q Penta H are two component (base paste/catalyst) materials to automatically be mixed in dispensed in 3M ESPE's Pentamix™ device. Poly Q Garant L is a material designed to be used in 3M ESPE's mixing, dosing and dispensing device, Garant™.

To provide evidence for safety biocompatibility testing was carried out. The results show that Poly Q is a safe device.

To prove the effectiveness of Poly Q, the performance characteristics of Poly Q Garant L, Poly Q Penta M and Poly Q Penta H were compared to the respective predicate devices.

In summary, the impression materials Poly Q Garant L, Penta M and Penta H, described in this 510(k) premarket notification submission, are, in our opinion, substantially equivalent to the respective predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 1 2003

Dr. Andreas Petermann
Regulatory Manager, U.S Affairs
3M ESPE AG
ESPE Platz
82229 Seefeld Bavaria,
GERMANY

Re: K032001
Trade/Device Name: Poly Q Garant L, Poly Q Penta M, and Penta H
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: II
Product Code: ELW
Dated: June 17, 2003
Received: June 27, 2003

Dear Dr. Petermann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K032001

Device Name: Poly Q (Poly Q Garant L, Poly Q Penta M, Poly Q Penta H)

Indications For Use:

Poly Q Garant L:

Wash material for dual phase impression techniques.

Poly Q Penta M:

Impression material for monophase technique.

Poly Q Penta H:

Tray material for dual phase impression techniques.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert S Baer DDS for Dr K. Mulay

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K032001

(Optional Format 3-10-98)